REMARKS

Allowed Subject Matter

Applicants gratefully acknowledge the Examiner's indication that claims 1-9, 13, 14, 16-26, 28, 36-47, and 52 are allowed.

Amendments

Claim 49 and page 33 of the specification are amended to correct an obvious typographical error.

Claims 29, 30, 34, 35, 48, 50, 51, and 53-55 are cancelled by the above amendments. Thus, the only claims pending that are not already allowed are claims 33 and 49. Applicants reserve the right to file a dvisional application directed to the cancelled subject matter.

Claim 33 is amended to recite a method of treating a patient suffering from inflammation, rather than treating a patient suffering from an allergic or inflammatory disease. Claim 49 depends from claim 33 and specifies what diseases/conditions have induced the inflammation.

New claims 56-57 depend from claim 49 and are directed to the treatment of inflammation due to specific conditions/diseases recited in claim 49.

Rejection under 35 USC 112, first paragraph

Claims 20, 30, 33-35, 48-51, and 53-55 are rejected as allegedly being non-enabled. This rejection is respectfully traversed.

Initially, it should be noted that the inclusion of claim 20 is assumed to be a typographical error. Instead, it appears that claim 29 was intended. For example, the "Office Action Summary" indicates that claim 20 is allowed and that claim 29 is rejected.

As noted above, claims 29, 30, 34, 35, 48, 50, 51, and 53-55 are cancelled. Thus, the only pending claims that are rejected are claims 33 and 49.

In the rejection, it is acknowledged that applicants' disclosure is enabling for "a method for enhancing cognition and a method for the treatment of inflammation and inflammation due to asthma and chronic obstructive pulmonary disease." Claim 33 is amended to recite a method of treating a patient that is suffering from inflammation.

Thus, the rejection acknowledges that claim 33, as amended, is enabled. Claim 49 and new claims 56-57 depend from claim 33 and thus also are enabled. Therefore, withdrawal of the rejection is respectfully requested.

In any event, applicants disagree with the assertion of nonenablement with respect to the cancelled claims. Method claims are inherently functional. In other words, the literal scope of the method claims encompass only those embodiments that achieve the specified function. See, e.g., *In re Angstadt*, 190 USPQ 214 (CCPA 1976) and *Dinn-Nguyen et al.*, 181 USPQ 46 (CCPA 1974).

Applicants' specification clearly discloses that the compounds in question are PDE4 inhibitors. The specification also discloses that these PDE4 inhibitors can be used to treat diseases and conditions for which PDE4 inhibitors are known in the art to have activity. No reason is presented in the rejection to doubt the veracity of these statements in applicants' disclosure. Furthermore, the disclosure provides more that adequate guidance for one of ordinary sill in the art to determine the relative amount of PDE4 activity for any given compound within the claimed methods using no more than routine experimentation.

An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enablement requirement of the first paragraph 35 U.S.C. § 112, unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana,* 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel,* 984 F.2d 1164, 24 USPQ2d 1601 (Fed. Cir. 1993). Furthermore, as stated in *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (CCPA 1971), the PTO must have adequate support for its challenge to the credibility of applicant's statements of enablement. See also *In re Bundy*, 209 USPQ 48 (CPA 1981).

As discussed above, the rejection does not provide reasons to doubt the veracity of statements in applicants' disclosure that the compounds possess PDE4 inhibitory activity. Further, the art recognizes that compounds possessing PDE4 inhibitory activity can be used to treat the diseases and/or conditions recited in the claims.

To establish the requisite objective enablement under the 35 USC 112, first paragraph, an applicants' disclosure is not required to present specific test results such as *in vivo* or *in vitro* test results. All that is required under the statute is **objective** enablement. See, e.g., *In re Marzocchi et al.*, at 369:

> The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

The MPEP is also in agreement with the holding in *Marzocchi.* The MPEP states that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

The test for enablement is not whether any experimentation is needed but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson,* 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988).

Merely because it is alleged that a specific example of treating a disease is not presented in the specification, one of ordinary skill in the art would not doubt the truth of the statements concerning the activity of the compounds. As noted above, MPEP § 2164.02 states that compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. The nature of the invention and the state of the art, as discussed above, further demonstrate that applicants' specification provides sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention.

With respect to guidance, applicants' specification provides more than sufficient guidance with respect to dosages, formulations, modes of administration, and assays for determining the relative amount of PDE4 inhibitory activity.

In view of the above remarks, it is respectfully submitted that applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with no more than routine

experimentation. The rejection does not present sufficient reasons to doubt the veracity of the enablement statements set forth in the disclosure.

In view of the above remarks, allowance of the instant application is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: MEMORY-29

Date: June 29, 2006